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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROY CURTISS III and STEVEN A. TINGE

Appeal 2009-014928
Application 09/120,970
Technology Center 1600

Decided: June 28, 2010

Before ERIC GRIMES, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of immunizing an animal, which the Examiner has rejected for nonenablement and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 30, 32, 33, 35-39, 50, 51, and 53-64 are on appeal.[1] Claims 30 and 61 are representative and read as follows:

30. A method for inducing an immune response in a warm-blooded animal comprising administering to the animal a composition comprising a bacterial cell, wherein

(a) the bacterial cell comprises an expression gene that encodes an antigen, and an Environmentally Limited Viability System,
(b) the antigen is introduced into the animal,
(c) the bacterial cell is viable when in the animal and non-viable when outside of the animal, and
(d) the Environmentally Limited Viability System comprises an essential gene that is under the control of an environmentally regulatable control sequence, wherein

(i) expression of the essential gene in the cell is essential to the viability of the cell,
(ii) the essential gene is expressed when the cell is in the animal and is not expressed when the cell is outside of the animal,
(iii) the essential gene is essential for metabolism, growth, cell wall integrity or cell membrane integrity of the bacterial cell, and
(iv) the essential gene is a copy of a native chromosomal gene wherein the chromosomal copy of said native gene is inoperable.

61. The method of claim 57, wherein the extrachromosomal vector comprises pMEG-104.

The claims stand rejected as follows:

- Claims 61-64 under 35 U.S.C. § 112, first paragraph, as nonenabled (Ans. 3) and

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[1] Claims 41-49 and 65 are also pending (Appeal Br. 4-5) but are not included in either of the Examiner's rejections.

• Claims 30, 32, 33, 35-39, 50, 51, and 53-60 for obviousness-type double patenting (*id.* at 4).

I.

The Examiner has rejected claims 61-64 on the basis that a deposit of plasmid pMEG-104 is required to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph (Ans. 3-4). However, we agree with Appellants that the Examiner has not adequately explained why undue experimentation would be required to construct pMEG-104 following the directions provided in the Specification. We reverse the rejection of claims 61-64 for the reasons set forth in the Appeal Brief, pages 17-19.

II.

The Examiner has rejected claims 30, 32, 33, 35-39, 50, 51, and 53-60 for obviousness-type double patenting based on claims 1-24 of U.S. Patent 6,780,405 because she concludes that the patented claims are a species encompassed by the claims on appeal (Ans. 4).

Appellants contend that "the claims on appeal are readily distinguishable and not obvious variants over the claims of the '405 patent" because the claims on appeal require environmentally regulatable expression of an essential gene, while the '405 patent's claims require "a dual-*ori* (one low copy, one high copy) runaway vector and at least one chromosome-encoded regulated repressor" (Appeal Br. 11).

Again, we find ourselves in agreement with Appellants' position. Claim 1 (the only independent claim) of the '405 patent reads as follows:

1. A microorganism comprising a regulated antigen delivery system (RADS), wherein the RADS comprises (a) a vector comprising (1) a gene

encoding a desired gene product inserted into a site for insertion of a gene encoding a desired gene product, wherein the gene encoding the desired gene product is operably linked to a second control sequence; (2) a first origin of replication (ori) conferring vector replication using DNA polymerase III; and (3) a second ori conferring vector replication using DNA polymerase I,

> wherein the second ori is operably linked to a first control sequence repressible by a first repressor, and wherein the runaway vector does not comprise a phage lysis gene; and
> (b) a gene encoding a first repressor operably linked to a first activatible control sequence.

Claim 24 of the '405 patent is the only claim directed to a method and reads as follows: "A method of inducing immunoprotection in a vertebrate comprising administering the vaccine of claim 19 to the vertebrate" ('405 patent, col. 52, ll. 11-13). Claim 19 ultimately depends from claim 1. Thus, the patented method requires administering microorganism comprising a "runaway vector" that comprises an origin of replication under the control of DNA polymerase III and a second, repressible origin of replication under the control of DNA polymerase I.

By contrast, claim 30 of the present case, the only independent claim on appeal, requires administering to an animal a bacterial cell that comprises an essential gene under the control of an environmentally regulatable control sequence, so that the gene is expressed when the cell is in the animal but not when the cell is outside the animal, with the result that the cell is viable only when it is in the animal.

Thus, while the presently claimed and patented methods are both intended to induce an immune response, they require administering different products. The Examiner has not adequately explained why the presently

claimed method of immunizing an animal by administering a cell that expresses an essential gene only when the cell is in the immunized animal is an obvious variant of a method of immunizing an animal by administering a microorganism comprising a runaway vector having the origins of replication that are required by the claims of the '405 patent.

SUMMARY

We reverse the rejection of claims 61-64 for nonenablement and the rejection of claims 30, 32, 33, 35-39, 50, 51, and 53-60 for obviousness-type double patenting.

REVERSED

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